UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STANLEY E. KATZ and ALAIN MARTIN

Appeal 2007-0054
Application 09/846,722
Technology Center 1600

ON BRIEF

Before ADAMS, GRIMES, and LINCK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a treatment method. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

"The inflammatory response, often referred to as respiratory bursting, is the response of defensive mammalian cells primarily white blood cells or leucocytes." (Specification 12.) "Reactive oxygen species are generated by cells in response to . . . the respiratory burst of phagocytic cells (such as

white blood cells) to kill invading bacteria and in response to foreign bodies." (*Id.* at 1.) "These active oxygen species can injure cells." (*Id.* at 2.) "Antioxidants have been shown to inhibit damage associated with active oxygen species." (*Id.* at 3.) Hydrogen peroxide is an example of an active oxygen species. (*Id.* at 13.)

The specification describes "a method for treating the disease state in mammals caused by mammalian nasal and sinus cells involved in the inflammatory response." (*Id.* at 11.) The method "comprises: contacting the mammalian nasal and sinus cells participating in the inflammatory response with an inflammatory mediator; wherein the inflammatory mediator is present in an amount capable of reducing the undesired inflammatory response and is an antioxidant." (*Id.*) "Typical diseases treatable by the present . . . method include but are not limited to rhinitis, eosinophilia syndrome, sinusitis and the like." (*Id.* at 18.)

The specification states that the preferred inflammatory mediator is pyruvate or a pyruvate precursor. "A precursor is a substance from which another substance is formed and . . . also includes salts." (*Id.* at 16.)

DISCUSSION

1. CLAIMS

Claims 1-6, 8-18, and 27-31 are on appeal. Claims 19-26 are also pending but have been withdrawn from consideration by the Examiner.

For each rejection, the claims have been argued as a group. Thus, the claims of each rejection stand or fall together. We will focus on claims 1, 18, and 27, which are representative and read as follows:

1. A method for treating a disease state in mammals caused by mammalian nasal and sinus cells involved in the inflammatory response

comprising contacting the mammalian nasal and sinus cells with an inflammatory mediator; wherein the inflammatory mediator is present in an amount capable of reducing the undesired inflammatory response, is an antioxidant, and is selected from the group consisting of pyruvate and a pyruvate precursors [sic], wherein the pyruvate precursor is not propylene glycol.

18. The method of claim [1, further comprising contacting the mammalian nasal and sinus cells with a therapeutic agent], wherein the therapeutic agent is oxymetazoline.

27. A method for the treatment of rhinitis, eosinophilia syndrome, and sinusitis, comprising administering a nasal solution to the nostrils of a patient in need thereof, wherein the nasal moisturizing saline solution comprises:

a) water,
b) sodium chloride, 0.65% by weight,
c) pyruvate, at least 0.1mM,
d) buffer, and optionally,
e) a preservative;

wherein the nasal moisturizing saline solution is buffered and made isotonic.

Thus, claim 1 is directed to a "method for treating a disease state in mammals caused by mammalian nasal and sinus cells involved in the inflammatory response." The method comprises contacting the nasal and sinus cells with pyruvate or a pyruvate precursor other than propylene glycol, "in an amount capable of reducing the undesired inflammatory response."

Claim 18 ultimately depends from claim 1 and recites that the nasal and sinus cells are also contacted with oxymetazoline.

Claim 27 is directed to a method for treating, among other things, sinusitis, by nasally administering a specified, pyruvate-containing solution.

2. CLAIMS 1-6, 8-17, AND 31

Claims 1-6, 8-17, and 31 stand rejected under 35 U.S.C. § 103 as obvious over Katz[1] in view of Amschler.[2] The Examiner states that "Katz teaches a method of treating a disease state in mammals caused by mammalian cells involved in the inflammatory response, which comprises contacting the mammalian cells involved in the inflammatory response with a therapeutically effective amount of an inflammatory mediator (col. 4, lines 58-67). The inflammatory mediators are taught to be antioxidants selected from pyruvates . . . and pyruvate precursors . . . (col. 7, lines 21-41)." (Answer 3.) The Examiner states that Katz "specifically teaches inhalation treatments for disorders such as bronchial asthma, bronchitis, etc." and "does not specifically teach the administration of the composition to the nasal cells." (Answer 4.)

The Examiner states that Amschler "teaches a method of treating inflammatory disorders of the lung (e.g. bronchitis, bronchial asthma, etc.) and inflammatory disorders of the nose (e.g. rhinitis, sinusitis, etc.) with an anti-inflammatory composition (col. 8, lines 36-57; col. 9, lines 61-68)." (Answer 4.)

The Examiner concludes that a person of ordinary skill in the art would have found it obvious to administer Katz's pyruvate-containing anti-inflammatory composition to treat inflammation of the nasal and sinus cavities because Amschler teaches administering anti-inflammatory compositions to treat such conditions. (Answer 4-5.) In particular, the

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[1] Katz, U.S. Patent No. 5,798,388, issued August 25, 1998.
[2] Amschler et al., U.S. Patent No. 5,449,676, issued September 12, 1995.

Examiner argues that "the skilled artisan, when examining the general teaching of Katz with the teaching of Amschler et al. that the inflammatory agents disclosed therein are known to be useful for both the treatment of inflammatory disorders of the lung and nose, would have been motivated by an expectation of success in treating inflammatory disorders of the nose with the methods and compositions of Katz." (Answer 9.)

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious. Katz describes "a method for treating the disease state in mammals caused by mammalian cells involved in the inflammatory response." (Col. 4, ll. 58-60.) The method comprises "contacting the mammalian cells participating in the inflammatory response with an inflammatory mediator; wherein the inflammatory mediator is present in an amount capable of reducing the undesired inflammatory response and is an antioxidant." (Col. 4, ll. 61-67.) Katz lists pyruvate and pyruvate precursors as preferred inflammatory mediators. (Col. 7, ll. 21-23.) The inflammatory mediator is preferably "administered locally to the site of inflammation." (Col. 6, ll. 45-47.) Katz states that "[t]ypical airway diseases treatable by the . . . method include but are not limited to bronchial asthma, acute bronchitis, . . . and the like." (Col. 7, l. 65, to col. 8, l. 10.)

Amschler describes compounds having anti-inflammatory activity that can be used for the treatment of bronchial disorders, such as bronchitis and bronchial asthma. (Col. 8, ll. 41-57.) Amschler states that the compounds can also be used to prevent and treat allergic or chronic reactions, such as rhinitis and sinusitis. (Col. 9, ll. 61-67.) We agree with the Examiner that one of ordinary skill in the art would have been motivated by the teachings

of Katz and Amschler to treat disease states caused by inflammation of nasal and sinus cells, such as rhinitis and sinusitis, by contacting the nasal and sinus cells with pyruvate or a pyruvate precursor.

Appellants argue that Katz "does not teach the treating of inflammatory disorders in the nose. It is not proper within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (Br. 7.)

In addition, Appellants argue that there is "no suggestion or motivation in the references of *Katz* or *Amschler et al.* or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to . . . combine [the] reference teachings in the manner proposed by the Examiner. Moreover, there is no reasonable expectation of success [in] combining *Katz* and *Amschler et al.* in the manner proposed by the Examiner." (Br. 9.)

In particular, Appellants argue that the "treatment of inflammatory disorders in the lung is very different from the treatment of inflammatory disorders in the nose and sinuses because of the different cell types and routes of metabolism." (Br. 6.) Specifically, Appellants state that:

> In the sinuses, nitric oxide and hydrogen peroxide are produced by epithelial cells which produce 1000x more nitric oxide and hydrogen peroxide than that produced in lung cells. . . . Thus the use of inflammatory mediators such as pyruvate or pyruvate precursors in the lungs and in the sinuses is quite different. In the lungs, excess pyruvate is transported into the cell and used as energy. . . . In the sinuses, excess pyruvate is used up in seconds by the very high concentrations of oxygen radicals.

> The main function of pyruvate and pyruvate precursors in the sinuses is to protect sinus medicines from destruction and to lower excess oxygen radicals.

(*Id.*)

Appellants also argue that, "[a]t best, *Amschler et al.* may teach that 3-amino-6-arylpyridazine compounds may be used to treat inflammatory disorders both in the lung and in the nose but *Amschler et al.* certainly does not teach that ALL compounds known to treat inflammatory disorders in the lung may be used in a similar manner to treat inflammatory disorders in the nose." (Br. 6-7.) Appellants argue that the "synthetic 3-amino-6-arylpyridazine compounds of *Amschler et al.* are in no way comparable to appellants' natural pyruvate compounds." (Br. 8-9.)

We are not persuaded by these arguments. Although Katz specifically describes treatments of inflammatory disorders of the lung, we agree with the Examiner that Katz is broader than this teaching. Katz generally teaches treating disease states caused by mammalian cells involved in the inflammatory response, which would include disease states caused by mammalian nasal and sinus cells involved in the inflammatory response.

In addition, Amschler teaches that some compounds can be used to treat inflammatory disorders of either the lung or the nose and sinuses, such as rhinitis and sinusitis. Amschler does not teach that pyruvate or pyruvate precursors can be used for the treatment of inflammatory disorders of both the lung and the nose and sinuses. However, in view of the broad teachings of Katz, we conclude that one of ordinary skill in the art would have been motivated to treat disease states caused by inflammation of the nasal and sinus cells, such as rhinitis and sinusitis, by contacting the nasal and sinus

cells with pyruvate or a pyruvate precursor. In addition, we conclude that the broad teachings of Katz combined with the teachings of Amschler provide a reasonable expectation of success.

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious over Katz in view of Amschler, which Appellants have not rebutted. We therefore affirm the rejection of claim 1 under 35 U.S.C. § 103. Claims 2-6, 8-17, and 31 fall with claim 1.

3. CLAIM 18

Claim 18 stands rejected under 35 U.S.C. § 103 as obvious over Katz in view of Amschler and Geria.[3] Claim 18 ultimately depends from claim 1 and recites that the nasal and sinus cells are also contacted with a therapeutic agent, oxymetazoline.

The Examiner relies on Katz and Amschler for the limitations of claim 1. The Examiner argues that Katz describes administering additional therapeutic agents "prior to, after and/or with the inflammatory mediator (col. 8, lines 13-18)." (Answer 4.) In addition, the Examiner argues that "Geria teaches that oxymetazoline is known for the treatment of rhinitis and sinusitis, particularly with the congestion associated therewith (col. 4, lines 1-15)." (Answer 5.) The Examiner concludes that the skilled artisan would have been motivated to include oxymetazoline with the inflammatory mediator to provide congestion relief, as well as reduce the inflammatory response, in patients suffering from sinusitis or rhinitis. (Answer 6.) We conclude that the Examiner has set forth a prima facie case that claim 18 would have been obvious.

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[3] Geria, U.S. Patent No. 5,478,565, issued December 26, 1995.

Appellants argue that the combination of Katz and Amschler does not provide a "method for treating a disease state in mammals caused by mammalian nasal and sinus cells involved in the inflammatory response," as recited in claim 1, and that Geria does not overcome this deficiency. (Br. 11.) However, for the reasons discussed above, we conclude that claim 1 would have been obvious in view of Katz and Amschler. Appellants have not rebutted the Examiner's prima facie case that claim 18 would have been obvious. We therefore affirm the rejection of claim 18 under 35 U.S.C. § 103.

4. CLAIMS 27-30

Claims 27-30 stand rejected under 35 U.S.C. § 103 as obvious over Katz in view of Amschler and Picciano.[4] We will focus on claim 27.

The Examiner argues that "the combined references render a method of treating sinusitis with inflammatory modulator [sic, mediator] compositions obvious." (Answer 7.) Katz describes pyruvate as an inflammatory mediator. (Col. 7, ll. 21-23.) The Examiner argues that "Picciano teaches the treatment of sinusitis with an isotonic buffered nasal saline solution comprising water, sodium chloride, 0.65% by weight, iodine, buffer and a preservative (col. 4, lines 52-59). . . . The solution is taught to alleviate congestion and to provide moisturization." (Answer 6-7.) The Examiner argues that the skilled artisan would have been motivated to include the inflammatory mediator (i.e., pyruvate) in the solution of Picciano to provide congestion relief and nasal moisturization, as well as reduce the inflammatory response, in patients suffering from sinusitis. (Answer 7.) We

[4] Picciano, U.S. Patent No. 5,897,872, issued April 27, 1999.

conclude that the Examiner has set forth a prima facie case that claim 27 would have been obvious.

Appellants argue that the combination of Katz and Amschler does not provide a "method for treating a disease state in mammals caused by mammalian nasal and sinus cells involved in the inflammatory response" and that Picciano does not overcome this deficiency. (Br. 12-13.) However, as discussed above, we conclude that one of ordinary skill in the art would have been motivated by the teachings of Katz and Amschler to treat disease states caused by inflammation of nasal and sinus cells, such as rhinitis and sinusitis, by contacting the nasal and sinus cells with pyruvate. Thus, we conclude that Appellants have not rebutted the Examiner's prima facie case that claim 27 would have been obvious. We therefore affirm the rejection of claim 27 under 35 U.S.C. § 103. Claims 28-30 fall with claim 27.

OTHER ISSUE

The application includes two claims 29. If this application is subject to further prosecution, the second claim 29 should be re-numbered as claim 30, with subsequent claims re-numbered accordingly. 37 C.F.R. § 1.126.

SUMMARY

The Examiner's position is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 1-6, 8-18, and 27-31 under 35 U.S.C. § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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Administrative Patent Judge)
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